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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/986,606	12/08/1997	NATHAN H. SLAONE	21578-013RCE	5146

30623 7590 03/04/2003

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EXAMINER
LUKTON, DAVID

ART UNIT	PAPER NUMBER
1653	41

DATE MAILED: 03/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/986,606	Applicant(s) Sloane
	Examiner David Lukton	Art Unit 1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 13, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *4-15* is/are pending in the application.

4a) Of the above, claim(s) *12-14* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *4-11 and 15* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 4-15 remain pending. Applicants election of Group I (4-11 and 15) without traverse is acknowledged. Claims 12-14 are withdrawn from consideration.

*

Applicants are reminded of the preferred arrangement of the specification.

(a) Title of the Invention.
(b) Cross-References to Related Applications.
(c) Statement Regarding Federally Sponsored Research or Development.
(d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
(e) Background of the Invention.
    1. Field of the Invention.
    2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).
(h) Detailed Description of the Invention.
(i) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing (see 37 CFR 1.821-1.825).

- The abstract should be presented on a sheet of paper which is separate from any other part of the specification. Accordingly, the first paragraph on page 2 of the specification should be deleted, and a new abstract provided. On the subject of the abstract, note that on line 8 (of the abstract) the following is recited:

"implanted in nude mice **(Sloane** Davis Tumor..."

Here, there is an unmatched left-handed parenthesis. Recititation of a reference in an abstract is not necessary, but if it is present, the parentheses should be matched.

- Page 1 of the specification is not numbered; in addition, information is provided on this page which is neither necessary nor desirable. Applicant should direct the

deletion of all information on this page other than the title.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-11 and 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Each of claims 4-11 and 15 is drawn to a peptide or composition or method. In each case, the claim is drawn to a peptide which comprises SEQ ID NO:1. There may be support in the specification for a peptide that consists of SEQ ID NO:1, but it does not appear that support exists for a peptide that comprises SEQ ID NO:1. Applicant is requested to point to the location in the text where support for this may be found.

A matter separate from the foregoing concerns claims 10 and 11. There does not appear to be support for killing cervical or laryngeal tumor cells using the peptide of SEQ ID NO: 1. It is true that cervical and laryngeal cells are mentioned in the abstract (page 2, specification). However, this is in reference to the full-length protein ANUP, rather than the peptide of SEQ ID NO: 1.

A matter unrelated to the foregoing concerns claim 15. Claim 15 is drawn to a method of activating a peptide by contacting the peptide with an unspecified detergent. Certainly, there is some support for using SDS in this regard, but it does not appear that there is descriptive support for any other detergent, or for detergents in general. Applicant is requested to point to the location in the text where support for this may be found.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 8-11 are drawn to a method of killing a tumor cell. These claims encompass killing both *in vitro* and *in vivo*. However, enablement is lacking, at least for the case of achieving the "contacting" by administering the peptide to a tumor-bearing mammal.

As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988), the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount

of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims. The following references discuss the matter of various attempts by oncologists to treat cancer: Viallet (*Lung Cancer* **15** (3) 367-73, 1996); Kemeny (*Seminars in Oncology* **21** (4 Suppl 7) 67-75, 1994); Newton (*Expert Opinion on Investigational Drugs* **9** (12) 2815-29, 2000); Giese (*Journal of Cancer Research and Clinical Oncology* **127** (4) 217-25, 2001); Garattini (*European Journal of Cancer* **37** Suppl 8 S128-47, 2001); Ragnhammar (*Acta Oncologica* **40** (2-3) 282-308, 2001).

As is evident, attempts to kill cancer cells in tumor-bearing mammals using agents which have exhibited *in vitro* activity leads to "unpredictable" results. In addition, applicant has made an admission (page 5, lines 1-2) that the peptide failed to kill tumor cells when SDS was absent. It is suggested that claim 8 be cancelled. If deemed appropriate, the following claim "100" could be added, or else either of claims "101" or "102":

> *100. A method of promoting apoptosis of tumor cells comprising contacting the tumor cells with with the peptide of SEQ ID NO: 1 for a time and under conditions effective to promote apoptosis of said tumor cells*
>
> *101. A method of killing a tumor cell in vitro comprising contacting said tumor cell with a composition for a time and under conditions effective to kill said tumor cell in vitro, wherein said composition comprises a peptide of SEQ ID NO: 1 in combination with sodium dodecyl sulfate.*
>
> *102. A method of killing a tumor cell in vitro comprising contacting said tumor cell*

with a composition comprising a peptide of SEQ ID NO: 1 and sodium dodecyl sulfate, wherein the tumor cell is contacted with said composition for a time and under conditions effective to kill said tumor cell in vitro.

*

Claims (5-11 and 15) are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 5 is drawn to an "agent". The term "agent" could refer to a single compound, or to a mixture of compounds, or a composition. Thus, there is some ambiguity. Furthermore, if the term "agent" is intended to refer to a composition (rather than a single compound) then the claim would implicitly mandate the presence of a second component, such as a "carrier". Accordingly, the claim is indefinite as to the identity of the second component. If there is descriptive support in the specification for a "carrier", then either of the following could be claimed (no determination has been made as to what might constitute new matter):

  A composition comprising a carrier and a peptide of SEQ ID NO: 1 in an amount effective to promote apoptosis of tumor cells.

  A composition comprising a peptide of SEQ ID NO: 1 in combination with a carrier.

- In claim 6, there is a minor typographical error "polyeptide".

- Claim 8 is not enabled, at least when the "contacting" is undertaken within a mammalian host; however, that is not the point of this rejection. This rejection stems from the fact that claim 8 is indefinite as to the process steps and endpoint. For example, if one had a petri dish containing a mass of tumor cells, and one were to add one picogram of the claimed peptide, and proceeded to incubate for a period of just 10 seconds, would a tumor cell be "killed" in that period? The following is suggested:

A method of promoting apoptosis of tumor cells comprising contacting the tumor cells with with the peptide of SEQ ID NO: 1 for a time and under conditions effective to promote apoptosis of said tumor cells

- Claim 15 is dependent on non-elected claim. It is suggested that claim 15 be written in independent form.

- Claim 15 is drawn to a method of "activating" a peptide. However, the claim is indefinite as to the manifestations of the activation.

*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800